



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,796	10/01/2001	David M. Goldenberg	IMMU:007US3	3640
37013 7590 06/01/2007 ROSSI, KIMMS & McDOWELL LLP. P.O. BOX 826 ASHBURN, VA 20146-0826			EXAMINER HARRIS, ALANA M	
			ART UNIT 1643	PAPER NUMBER
			MAIL DATE 06/01/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/965,796	Applicant(s) GOLDENBERG, DAVID M.	
	Examiner Alana M. Harris, Ph.D.	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-27, 36-44, 47, 52 and 55-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-27, 36-44, 47, 52 and 55-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Claims 24-27, 36-44, 47, 52 and 55-59 are pending.

Claims 24-27, 36-44, 47, 52 and 55-59 are examined on the merits:

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Rejections

Claim Rejections - 35 USC § 103

3. The rejection of claims 24-26, 36-38, 44, 47, 52 and 55-57 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 5,789,554 (filed July 31, 1996), and in further view of Maloney et al. (Blood 84(8): 2457-2466, October 15, 1994/ IDS reference A11) and Li et al. (Cellular Immunology 118: 85-99, 1989) is withdrawn in light of Applicant's arguments.
4. The rejection of claims 24-27, 36-38, 44, 52 and 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 5,789,554 (filed July 31, 1996), and further in view of Maloney et al. (Blood 84(8): 2457-2466, October 15, 1994/ IDS reference A11) and U.S. Patent number 5,106,955 (April 21, 1992) is withdrawn in light of Applicant's arguments.

Art Unit: 1643

5. The rejection of claims 24-26, 36-42, 44, 52 and 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 5,789,554 (filed July 31, 1996), in view of Maloney et al. (Blood 84(8): 2457-2466, October 15, 1994/ IDS reference A11), U.S. Patent Number 5,686,072 (filed February 22, 1994/ IDS reference A1) and WO 95/09917 (April 13, 1995/ IDS reference A5) is withdrawn in light of Applicant's arguments.

6. The rejection of claims 24-26, 36-39, 44, 52 and 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 5,789,554 (filed July 31, 1996), in view of in view of Maloney et al. (Blood 84(8): 2457-2466, October 15, 1994/ IDS reference A11) and European Patent Application 0 510 949 A2 (October 28, 1992/ IDS reference A4) is withdrawn in light of Applicant's arguments.

7. The rejection of claims 24-27, 36-38, 43, 44, 52 and 55-59 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 5,789,554 (filed July 31, 1996), and further in view of Maloney et al. (Blood 84(8): 2457-2466, October 15, 1994/ IDS reference A11) and U.S. Patent number 5,698,178 (filed April 8, 1998) is withdrawn in light of Applicant's arguments.

8. The rejection of claims 24-27, 38, 43, 44, 52 and 55-59 under 35 U.S.C. 103(a) as being unpatentable over WO 96/04925 (22 February 1996/ IDS reference A8), and further in view of Maloney et al. (Blood 84(8): 2457-2466, October 15, 1994/ IDS

reference A11) and U.S. Patent number 5,698,178 (filed April 8, 1998) is withdrawn in light of Applicant's arguments.

Maintained and New Grounds of Rejection

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 24-26, 36-38, 44, 47, 52 and 55-57 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 5,789,554 (filed July 31, 1996), and in further view of Maloney et al. (Blood 84(8): 2457-2466, October 15, 1994/ IDS reference A11) and Li et al. (Cellular Immunology 118: 85-99, 1989). U.S. Patent number 5,789,554 teaches "[c]onjugates of chimeric and humanized chimeric LL2 antibodies with cytotoxic agents or labels..., use[d] in therapy..., of B-cell lymphomas and leukemias", see last sentence of the Abstract and column 2, lines 56-62. It is art known that LL2 antibodies are anti-CD22 monoclonal antibodies. The patent reveals the implementation of fragments from both human and murine immunoglobulin chains in methods of treatment, see column 2, lines 37-50; column 2, line 65-column 3, line 15.

These antibodies of the taught method could be attached to cytotoxic agents, as well as chemotherapeutic drugs, chelators, fluorescent molecules, radionuclides or toxins, see column 5, lines 20-28; Example 9 of columns 19 and 20 and with

Art Unit: 1643

particularity lines 9-18 in column 20. The disclosed antibodies can be conjugated to a ^{131}I radioisotope, as well as ^{90}Y or ^{111}In using a chelating agent, see column 9, lines 35-40; column 20, lines 35-42.

The patent does not teach a method for a subject having a B-cell malignancy, wherein the immunoconjugate comprises both, at least one human, humanized or chimeric anti-CD22 antibody or a fragment thereof and a naked anti-CD20 monoclonal antibody. U.S. Patent '554 also does not teach a therapeutic composition comprising at least two monoclonal antibodies that bind distinct CD22 epitopes.

However, Maloney teaches a method for treating B-cell lymphoma, Non-Hodgkin's lymphoma (NHL), as well as other leukemias and lymphomas with a chimeric anti-CD20 monoclonal antibody (also known as a naked anti-CD20 monoclonal antibody, IDEC-C2B8, C2B8, RITUXAN® (rituximab)) with a dosage ranging from 10-500mg/m², see abstract. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to administer a therapeutic combination of anticancer agents to effectively treat B cell malignancies, Maloney, see page 2465, last paragraph. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in both references, that each antibody was effective in treating B cell malignancies and a mixture of antibodies to the different epitopes of would be more efficacious in therapeutic methods, as well as enhance the treatment modality, see both documents. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings of all the references to combine the antibodies of the patent and Maloney.

Art Unit: 1643

Further, it is within the purview of one skilled in the art to combine different components that have similar end results. See MPEP § 2144.06, where it is stated that "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850,205 USPQ 1069, 1072 (CCPA 1980).

Moreover, Li teaches that four anti-CD22 monoclonal antibodies, UV22-1, UV22-2, HD6 and RFB47 recognize CD22 A and B epitopes. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to administer a combination of antibodies to different CD22 epitopes, as taught in the Li reference in the method of treating B cell malignancies as taught in the patent. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in the Li reference, that a mixture of antibodies to the different epitopes of CD-22 would be a more efficacious in therapeutic methods, as well as enhance the treatment modality.

11. Claims 24-27, 36-38, 44, 52 and 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 5,789,554 (filed July 31, 1996), and further in view of Maloney et al. (Blood 84(8): 2457-2466, October 15, 1994/IDS reference A11) and U.S. Patent number 5,106,955 (April 21, 1992). The teachings of patent #5,789,554 and Maloney have been presented in the previous cited 103(a) rejection. Those two

Art Unit: 1643

references did not teach a method for treating a B-cell malignancy wherein the therapeutic composition comprises specifically chemotherapeutic drugs, a nitrosourea derivative, hormones and an antiviral toxin linked via crosslinking agents.

However, U.S. patent #5,106,995 teaches the specific chemotherapeutic drugs, nitrosourea and hormones and antiviral toxins, see entire page with columns 5 and 6. It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to administer a therapeutic combination of a known anticancer antibody with other anticancer molecules in the method of treating B cell malignancies, as taught in both patents. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in the patents that conjugates of anti-CD22 antibodies and anti-CD20 mabs with anticancer agents are efficacious in the treatment of B-cell lymphomas and leukemias, see patent '554, abstract and Example 9 of columns 19 and 20; Maloney, page 24t5b, column 1, last paragraph; and patent '955, abstract and columns 5 and 6.

12. Claims 24-26, 36-42, 44, 52 and 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 5,789,554 (filed July 31, 1996), in view of Maloney et al. (Blood 84(8): 2457-2466, October 15, 1994/ IDS reference A11), U.S. Patent Number 5,686,072 (filed February 22, 1994/IDS reference A1) and WO 95/09917 (April 13, 1995/IDS reference A5).

The teachings of patent '554 and Maloney have been described in the initial 103(a) rejection. These references do not teach a multivalent fusion protein that

Art Unit: 1643

additionally comprises at least one antibody component that binds with CD19 or a trivalent, tetravalent or pentavalent fusion.

However, U.S. patent #5,686,072 teaches the administration of an unconjugated anti-CD19 antibody (also regarded as a naked antibody), toxins (ricin, diphtheria toxins in a mixture with anti-CD22 for the immunotherapeutic treatment of cancer, see abstract. It would have *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine an anti-CD19 antibody with an anti-CD22 antibody as taught in patent '072. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of both patents that the co-administration of anti-CD19 and anti-CD22 antibodies appears to provide a synergistic and advantageous cancer treatment, see both patents.

The WO document teaches that recombinant bispecific tetravalent antibodies are useful in both therapeutic and immunodiagnostic applications and can be produced with relative ease.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of claimed invention to produce a tetravalent construct comprising anti-CD22 antibodies, as well as trivalent and pentavalent fusion proteins. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in both patents and the WO document that tetravalent antibody constructs are more effective than monoclonal antibody to effectively target more antigenic sites on the cancer cells and to advantageously increase the avidity of antigen binding.

Art Unit: 1643

13. Claims 24-26, 36-39, 44, 45, 52 and 55-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 5,789,554 (filed July 31, 1996), in view of in view of Maloney et al. (Blood 84(8): 2457-2466, October 15, 1994/IDS reference A11) and European Patent Application 0 510 949 A2 (October 28, 1992/IDS reference A4). Claims 28-35, 46, 48-51, 53, 54 and 90 have been cancelled.

The teachings of patent '554 and Maloney have been described in the initial 103(a) rejection. These references do not teach a therapeutic composition comprising the said anti-CD22 antibody and an immunomodulator, such as a CD19 antibody component and toxins.

However, EP 0 510 949 A2 teaches conjugate formulas comprising two moieties, wherein both have physiological activity, see column 3, lines 3-6. The moieties may be an antibody and fragments thereof, interleukins 1-10, molecules that bind CD19 (regarded by the Examiner as an antibody), growth factors, GM-CSF, G-CSF and toxins (i.e., ricin, diphtheria toxins) in a mixture with anti-CD22 for the immunotherapeutic treatment of cancer, see abstract and column 3, lines 24-47. It would have prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to combine efficacious anti-tumor agents within an anti-cancer therapeutic composition. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of both patents that such conjugate compositions provide a synergistic and advantageous cancer treatment, see both patents.

Art Unit: 1643

14. Claims 24-27, 36-38, 43, 44, 52 and 55-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 5,789,554 (filed July 31, 1996), and further in view of Maloney et al. (Blood 84(8): 2457-2466, October 15, 1994/IDS reference A11) and U.S. Patent number 5,698,178 (filed April 8, 1998).

The teachings of patent '554 and Maloney have been described in the initial 103(a) rejection. These references do not teach a method for treating a subject having a B-cell malignancy comprising a therapeutic composition comprising a chemotherapeutic drug, immunomodulator, antiviral drugs, radioisotope, boron addend, anti-bacterial drug and photoactive agent or dye, as well as specific modes of attaching these molecules. Moreover, patent '554 and Maloney do not teach the administration of the immunoconjugate comprising an anti-CD22 antibody with radioisotopes iodine and yttrium in the specific dosages set forth in claims 94-97.

However, U.S. patent #5,698,178 teaches specific radioisotopes, ^{198}Au , ^{32}P , ^{125}I , ^{90}Y , ^{186}Re , ^{188}Re , ^{67}Cu and ^{211}At ; toxins, ricin A-chain, *Pseudomonas* endotoxin, gelonin, ribonuclease, abrin, and pokeweed antiviral protein; chemotherapeutic drugs, nitrogen mustard, alkyl sulfonates, nitrosoureas, triazenes, folic acid analogs, antibiotics, platinum coordination complexes, hormones, pyrimidine analogs; boron addends, such as carboranes; and immunomodulators, granulocyte-colony stimulating factor (G-CSF), GM-CSF, IL-1 and IL-3, see, see column 4, lines 35-56; column 6, lines 15-19; column 8, lines 26-36; column 16, line 59-column 17, line 2; column 23, line 11-column 24, line 6; column 31, lines 34-37. The patent also teaches the use of fluorescent chromogens or dyes, such as porphyrins in therapy termed photoradiation

Art Unit: 1643

or photodynamic therapy in order to destroy a tumor population, see column 24, lines 7-31, 45-54. Patent '178 also teaches modes of attaching the therapeutic agents to the antibodies and antibody fragments, $F(ab')_2$, $F(ab)_2$, Fab' and Fab via chelators such as ethylenediaminetetraacetic acid, DPTA, polyethyleneglycol, TETA and a carrier polymer such as aminodextran, see column 15, lines 56-67; column 17, lines 57-67; column 20, lines 28-34; and column 23, lines 19-31. Attachment of therapeutic agents to anti-CD22 antibodies may be implemented via a free sulfhydryl group, see column 14, lines 28-38 and column 17, lines 57-67. It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to administer a therapeutic combination of a known anticancer antibody with other anticancer molecules in the method of B cell treatment.

Additionally, it would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to administer the naked anti-CD22 antibody in the recited dosages. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings well known in the art, that dosages of any pharmaceutical composition must be adjusted and optimized.

15. Claims 24-27, 38, 43, 44, 52 and 55-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/04925 (22 February 1996/IDS reference A8), and further in view of Maloney et al. (Blood 84(8): 2457-2466, October 15, 1994/ IDS reference A11) and U.S. Patent number 5,698,178 (filed April 8, 1998).

The WO document teaches immunoconjugates comprising chimeric and humanized LL2 antibodies with cytotoxic agents, labels, as well as therapeutic agents attached indirectly via linkages in therapy of B-cell lymphomas and leukemias, see Abstract and page 1, lines 5-12; page 3, line 31-page 4, line 13; page 7, lines 27-38; and page 33, lines 15-24. The document reveals the implementation of fragments from both human and murine immunoglobulin chains in methods of treatment, see page 3, line 24-page 4, line 5; page 4, lines 14-32. A wide variety of diagnostic and therapeutic reagents can be conjugated to the disclosed antibodies such as doxorubicin, taxol, chelators, detectable labels such as fluorescent molecules, cytotoxic agents such as heavy metals or radionucleoides and toxins such as Pseudomonas exotoxin, see page 8, lines 17-26; page 33, lines 3-11 ; and page 33, line 33-page 34, line 10. The disclosed antibodies can be conjugated to a radioisotope other than ^{131}I for example ^{90}Y or ^{111}In using a chelating agent, see page 34, lines 3-10. The WO document does not teach a method for a subject having a B-cell malignancy, wherein the immunoconjugate comprises both, at least one human, humanized or chimeric anti-CD22 antibody or a fragment thereof and a naked anti-CD20 monoclonal antibody. Moreover, WO document 96/04925 does not teach the administration of the immunoconjugate comprising an anti-CD22 antibody with radioisotopes iodine and yttrium in the specific dosages set forth in claims 94-97.

However, Maloney teaches a method for treating B-cell lymphoma, Non-Hodgkin's lymphoma (NHL), as well as other leukemias and lymphomas with a chimeric anti-CD20 monoclonal antibody (also known as a naked anti-CD20 monoclonal

Art Unit: 1643

antibody, IDEC-C2B8, C2B8, RITUXAN® (rituximab)) with a dosage ranging from 10-500mg/m², see abstract. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to administer a therapeutic combination of anticancer agents to effectively treat B cell malignancies, Maloney, see page 2465, last paragraph. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in both references, that each antibody was effective in treating B cell malignancies and a mixture of antibodies to the different epitopes of would be more efficacious in therapeutic methods, as well as enhance the treatment modality, see both documents. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings of all the references to combine the antibodies of the patent and Maloney. Further, it is within the purview of one skilled in the art to combine different components that have similar end results. See MPEP § 2144.06, where it is stated that "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

However, U.S. patent #5,698,178 teaches specific radioisotopes, ¹⁹⁸Au, ³²P, ¹²⁵I, ⁹⁰Y, ¹⁸⁶Re, ¹⁸⁸Re, ⁶⁷Cu and ²¹¹At; toxins, ricin A-chain, *Psuedomonas* endotoxin gelonin, ribonuclease, abrin, and pokeweed antiviral protein; chemotherapeutic drugs, nitrogen mustard, alkyl sulfonates, nitrosoureas, triazenes, folic acid analogs, antibiotics,

Art Unit: 1643

platinum coordination complexes, hormones, pyrimidine analogs; boron addends, such as carboranes; and immunomodulators, granulocyte-colony stimulating factor (G-CSF), GM-CSF, IL-1 and IL-3, see, see column 4, lines 35-56; column 6, lines 15-19; column 8, lines 26-36; column 16, line 59-column 17, line 2; column 23, line 11-column 24, line 6; column 31, lines 34-37. The patent also teaches the use of fluorescent chromogens or dyes, such as porphyrins in therapy termed photoradiation or photodynamic therapy in order to destroy a tumor population, see column 24, lines 7-31,45-54. Patent '178 also teaches modes of attaching the therapeutic agents to the antibodies and antibody fragments, F(ab')₂, F(ab)₂, Fab' and Fab via chelators such as ethylenediaminetetraacetic acid, DPTA, polyethyleneglycol, TETA and a carrier polymer such as aminodextran, see column 15, lines 56-67; column 17, lines 57-67; column 20, lines 28-34; and column 23, lines 19-31. Attachment of therapeutic agents to anti-CD22 antibodies may be implemented via a free sulfhydryl group, see column 14, lines 28-38 and column 17, lines 57-67. It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings of both documents to administer a therapeutic combination of a known anticancer antibody with other anticancer molecules in the method of B cell treatment.

Additionally, it would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to administer the naked anti-CD22 antibody in the recited dosages. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings well known in

Art Unit: 1643

the art, that dosages of any pharmaceutical composition must be adjusted and optimized.

Double Patenting

16. The provisional rejection of claims 24-27, 36-44, 47, 52 and 55-59 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 24-44 of copending Application No. 10/314,330 (filed December 9, 2002) is maintained.

Applicant requests for the instant rejection to be held in abeyance until indication of allowable subject matter has been indicated at which time they would consider filing a terminal disclaimer.

The request has been considered. At this point in prosecution the rejection is maintained for the reasons of record.

17. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1643

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.

PRIMARY EXAMINER



Alana M. Harris, Ph.D.

24 May 2007